

2nd DRAFT

PRIVILEGED AND CONFIDENTIAL

16th April, 1986

For the Attention of Messrs. L. Pollak and B.B. Brooks.

A. Comments on :

Draft dated March 27, 1986, Part E.

Suggestions for Alternative Answers.

QA 1 : No comment

QA 2 : The use of ingredients in tobacco is comparable to adding spices to food. It is documented as far back as historic records are available. In fact, most of the principal processing aids, casing materials and flavourants, have not changed for decades. Of course, as consumer preferences evolve over time, there is also an evolution of the recipes for ingredients used in cigarettes.

QA 3 : Many of the ingredients on the list submitted to HMS are natural products such as fragrances extracted or distilled from plant materials. A simple aromatic essence derived from one kind of flower or fruit typically consists of dozens of substances which each are present in minute amounts but which contribute to its bouquet. The result of this is, that a fairly long list of individual compounds is

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necessary in order to define any one of such such natural ingredients. Because of their intensive aromatic properties, such fragrances can only be used in extremely small quantities, [which, as a rule, makes their detection by chemical means nearly impossible (This is why the flavour experts with their trained noses are still indispensable)]. Only about fifteen ingredients, mainly casing materials and humectants, are used in more substantial quantities. They may add up to about 99 percent in quantity of all ingredients submitted on the HMS list.

QA 4 : Most ingredients, e.g. natural fragrances and essences, are found in the final cigarette in only microgram or even nanogram amounts. Very few ingredients, e.g. casing materials, could reach the level of several milligrams per cigarette. Certain ingredients which serve as processing aids during the early stages of manufacturing ~~are removed~~ ^{generally disappear} before the product reaches its final form. The residual amounts of such processing aids in the final cigarette will be small and often undetectable. A small number of casing materials, humectants and flavourants account for most the ingredients actually used in cigarettes.

QA 5 : Consumer preferences in the recent past have, in general, shifted towards lower tar cigarettes. For some products of the lower tar category the ~~use of~~ ^{may} ingredients ~~might~~ ^{may} play ~~an even more~~ ^{a more} important role in consumer acceptance than was the case for products in the past. However, in quantitative terms, there is no evidence ~~that suggests~~ ^{that suggests} increased use of ingredients in such products. [The majority of flavourants are natural products such as fragrances extracted or distilled from plant materials. Because of their intensive aromatic properties, such fragrances can

This appears to be an overstatement. Moreover, we see no help in referring to flavor experts. We would eliminate.

We would eliminate bracketed material, rough top of p. 3.

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only be used in extremely small quantities, which, as a rule, makes their detection by chemical means nearly impossible. These ingredients will normally constitute less than one tenth of one percent by weight of the final product.

X
QA 6 : The majority of ingredients submitted on the HMS list are not specific to cigarettes but are used widely in foods, cosmetics and other consumer products. Although there was no specific list of cigarette ingredients issued as such in the past, handbooks and other technical publications deal with ingredients not only in describing their properties but also in explaining in detail their usage in food, cosmetics and tobacco.

Whilst information on the nature of ingredients used in cigarettes was always available to the public, the exact composition of proprietary recipes (flavour formulations) was not. However, this is not the case for other categories of consumer products either.

Because they contribute [no comment to the remainder of the answer].

QA 7 : No specific comment.

Not helpful, + not accurate as far as U.S. is concerned.
X
QA 8 : [In principle, the consumers, being part of the public, have always had access to published information on the use of ingredients in cigarettes.] It was obviously not always easy in the past, sometimes even for the expert, to obtain a complete, detailed and updated overview on the subject of ingredients. However this has changed as the latest scientific information becomes continuously available "on-line" through specialised information services.

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*This is contrary
to our view
that this
should continue
to be confidential.*

this sense, the list submitted to HHS, once reviewed, completed and updated annually, might become a source of additional information. ~~However, it is open to debate to what degree the lay public can make use of detailed technical information in highly specialised areas such as the field of cigarette ingredients.~~ *We doubt that*

Whilst information on the nature of ingredients used in cigarettes was always available to the public, the exact composition of proprietary recipes (flavour formulations) was not. However, this is not the case for other categories of consumer products either, and the reason is simply the highly competitive nature surrounding flavour recipes.

QA 9 : No comment.

QA 10 : No comment.

QA 11 : There are a number of countries in the world where regulations on the use of ingredients in consumer goods, including cigarettes, exist. In such markets, the importers comply with local regulations. In the majority of these cases, there is no necessity of changing the proprietary recipes, because the formulations for domestic US use also comply with local regulations.

In some cases, some minor adjustments of the recipes for ingredients might be necessary, because local regulations reflect the local history in the use of ingredients based on local taste preferences which might differ slightly from US practices.

In many export countries there are no specific regulations

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Is this
accurate?

on the use of ingredients in cigarettes and, as a rule, the product exported from the US are most likely to be the same as for domestic US use.

However, due to the proprietary nature of individual recipes, an exact answer to this question cannot be given.

QA 12 : The information available on ingredients in the published technical literature also includes ingredients used in cigarette filters. The Federal Cigarette Labeling and Advertising Act only requires that information be submitted concerning ingredients added to the tobacco used in cigarettes sold in the United States. We have therefore not compiled information on ingredients which might be added to other portions of the cigarette.

We would
eliminate; we
do not see
what is gained
by volunteering
this.

However, based on the information available in the published technical literature on this subject, the volatile ingredients added to filters e.g. fragrances, are essentially the same as the volatile ingredients used in the tobacco portion of the cigarette.

Other ingredients, which are largely non-volatile and are predominantly on the filter materials, are used for non-flavouring purposes such as structural stiffening of the fibrous part of the filter or for improving the filtration properties.

this is not
accurate if
we include the
pyrolysis issue.
II

QA 13 : There is a continuous flow of scientific information in the published literature on the safety evaluation of ingredients which are used in consumer products, and the scientific community continuously reviews the emerging data which leads to a consensus on the safety of the use of ingredients. In taking note of the available evidence.

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companies have no reason to believe that the use of ingredients in cigarettes could be harmful to the smoker.

QA 14 : Excellent answer, no comment.

QA 15 : If by "historic use" former centuries are meant, a precise answer is difficult to give, because the nomenclature used for ingredients was neither uniform nor precise. However, the scientific evaluation of the use of ingredients during recent decades do not give any reason to believe that the ingredients used in cigarettes in the more recent past could have been harmful to the smoker.

*We do not
believe this
is accurate, &
we would
eliminate*

X

QA 16 : [Longstanding use of an ingredient also means longstanding scrutiny by scientific methods, as any review of the published scientific literature demonstrates.] Indeed, most of the ingredients of cigarettes are either foods or approved for the use in the manufacture of food products or of other consumer products, and test data are available in the published scientific literature - now even available "on-line" through computerised information services.

Based on the available evidence, companies have no reason to believe that the use of ingredients in cigarettes could be harmful to the smoker.

QA 17 : In reviewing the published scientific literature on the safety evaluation of ingredients to cigarettes, companies have had no reason to believe that the use of ingredients in cigarettes could be harmful to the smoker nor, indeed, to the non-smoker.

QA 18 : The safety evaluation of any commodity used for


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human consumption does not necessarily consist of specific toxicologic testing, but includes chemical and other scientific considerations. This is why not each single ingredient has necessarily undergone a specific testing procedure as such. This, however, does not mean that its use is indiscriminate or arbitrary.

QA 19 : [I would not offer voluntarily an assortment of nice tests, hence my proposal.]

The safety evaluation of ingredients for consumer products is a highly complex procedure in which specialists of many scientific disciplines are involved. There are a considerable number of scientific institutes in the world who specialise in individual aspects of ingredient testing based on their expertise in specific methodologies. The results of their work are continuously being published and available "on-line" through established channels of scientific information.

Only the review of the consolidated scientific information on all relevant aspects, ranging from chemistry to toxicology, permits scientists to draw conclusions on the safety-for-use of ingredients.

QA 20 : There are two major misconceptions contained in the question.

a. Not all ingredients added to cigarettes are pyrolysed. In fact, the majority of ingredients are natural volatile fragrances which are produced by extraction or distillation from plant materials. In the burning cigarette they are volatilised and distilled into the smoke. Indeed, if they were pyrolysed, they would no longer fulfil their flavouring purposes.

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b. The non-specialist does probably not realise that the process of pyrolysis of organic materials starts at about 100°C and is almost completed when temperatures rise past 250°C, although residual pyrolytic activities are still found around 400°C.

As pyrolysis is, comparatively speaking, a low temperature process - as against combustion which occurs at temperatures of around and above 900°C - it is also ongoing in food products which are baked, roasted or grilled. In fact, the specific culinary characteristics which distinguishes each dish, from hamburgers to "haute cuisine", is largely the result of thermal processes in the temperature range between 100°C and 250°C.

When considering pyrolysis, the elementary chemical composition of a compound is of prime importance. In fact, the majority of ingredients listed in the submission to HMS contains only carbon, hydrogen and oxygen, some contain also nitrogen and only very few contain other elements. This means that the use of ingredients in cigarettes is unlikely to modify the composition of tobacco smoke in a significant way, a fact which has been supported by research data.

In addition, tests have been carried out with ingredients added to cigarette at much higher levels than normally applied in commercial use. The results obtained from this research on elevated ingredient levels have not given any reason either to believe that the use of ingredients in cigarettes could be harmful to the smoker.

QA 21 : No comment.

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QA 22 : No comment.

X

QA 23 : The safety evaluation of ingredients is a highly complex, ~~procedure~~^{involving} which specialists of many scientific disciplines, ~~are involved.~~ There are a considerable number of ~~scientific~~^{various} institutes in the world who specialise in ~~individual aspects~~^{specific kinds} of ingredient testing based on the their expertise in specific methodologies, including the different routes of application. The results of their work are continuously being published and available ~~"on-line"~~^{are} through ~~established channels of scientific information.~~^{in the scientific literature} Only the review of the consolidated scientific information, ~~on all relevant aspects,~~ ranging from chemistry to toxicology, permits scientists to draw conclusions on the safety-for-use of ingredients. In this context it must be appreciated that not all ingredients added to cigarettes are pyrolysed. In fact, the majority of ingredients are natural volatile fragrances which are commercially produced by extraction or distillation from plant materials. In the burning cigarette they are volatilised and distill into the smoke. Indeed, if they were pyrolysed, they would no longer fulfil their flavouring purpose.

QA 24 : No comment.

X

QA 25 : The safety evaluation of ingredients is a highly complex procedure in which specialists of many scientific disciplines are involved. There are a considerable number of scientific institutes in the world who specialise in individual aspects of ingredient testing based on the their expertise in specific methodologies, including the different routes of application. The results of their work are continuously being published and available "on-line" through established channels of scientific information. This work

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is ongoing and results continue to be published. There is no reason to believe that this would change in the future.

QA 26 : The assumptions underlying the question are not entirely correct because thermal processed do play a considerable role in food chemistry and are considered in great detail by experts in the field. On the other hand, the majority of ingredients which are added to cigarettes are not pyrolysed. In fact, the majority of ingredients are natural volatile fragrances which are produced by extraction or distillation from plant materials. In the burning cigarette they are volatilised and distill into the smoke without being changed chemically. Indeed, if they were pyrolysed, they would no longer fulfil their flavouring purpose.

The inclusion of ingredients on lists of substances approved for food use by FEMA or FDA indicates that a comprehensive scientific review has taken place and that the ingredient is suitable for human consumption. It may be appropriate to consider other types of data as well, but FDA's and FEMA's approval of the ingredient should receive considerable weight.

QA 27 : The use of ingredients in cigarettes in the Federal Republic of Germany is regulated by the German Food Law and its subordinated ordinances such as the Tobacco Ordinance, the Ordinance on Essences and Fragrances, etc. There has been a long historic evolution dating back to the years before World War II. The Federal Office of Health, a government agency comparable to the FDA, reviews the scientific data which lead to the inclusion of an ingredient in one of the lists of ingredients authorised for the use in cigarettes.

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The "First Report of the Independent Scientific Committee (ISC) on Smoking and Health" was published in the United Kingdom in 1975. It contains three lists of ingredients which are considered as authorised under the system of "Voluntary Agreements" between individual companies and H.M. Government (Department of Health and Social Security, DHSS). Considerable work had gone into the compilation of the lists. For each ingredient with a history of world-wide use in cigarettes of 20 years or more, a detailed data file was compiled at the Secretariat of the ISC (located at the DHSS), and which consists of data on its identity, origin, purity, level of use, toxicology, etc. The members of the ISC then reviewed the data available for each ingredient and issued their lists of authorised ingredients. At the same time, the ISC established guidelines for the approval for additional ingredients in the future.

QA 28 : Most of these ingredients serve as processing aids, casing materials or humectants. Processing aids will remain in the final cigarettes only in extremely small and often undetectable quantities.

Casing materials, which contribute towards a satisfactory taste and texture, and humectants, which serve to maintain cigarettes at the right moisture level during storage, include ingredients which are pyrolysed. When considering pyrolysis, the elementary chemical composition of a compound is of prime importance. In fact, the majority of casing materials and humectants listed in the submission to HHS contains only carbon, hydrogen and oxygen. This means that their use in cigarettes is unlikely to modify the composition of tobacco smoke in a significant way, a fact which has been supported by research data.

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Based on the available evidence, companies have no reason to believe that the use of casing materials or humectants in cigarettes could be harmful to the smoker.

QA 29 : No comment.

Answers 30 & 31 in I+E memo were deficient in which could be constructed

QA 30 : No comment other than this is not a good answer because it begs a question : Why does one not add the answer given to question 31 ?

QA 31 : No comment.

QA 32 : No comment.

QA 33 : No comment.

QA 34 : There is a continuous flow of scientific information in the published literature on the safety evaluation of ingredients which are used in consumer products. The scientific community continuously reviews the emerging data which leads to an informed consensus amongst experts on the safety-for-use of ingredients. Based on the available evidence, companies have no reason to believe that the use of ingredients in cigarettes could be harmful to the smoker.

QA 35 : No comment.

QA 36 : The industry has not acted in a nonchalant way. In fact, the contrary is true. The safety evaluation of ingredients for consumer products is a highly complex procedure in which specialists of many scientific disciplines are involved. There are a considerable number of scientific institutes in the world who specialise in the individual aspects of ingredient testing based on the the

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X

expertise in specific methodologies. The results of their work are continuously being published and available "on-line" through established channels of scientific information. Only the review of the consolidated scientific information on all relevant aspects, ranging from chemistry to toxicology, permits scientists to draw conclusions on the safety-for-use of ingredients.

It is based on this evidence that cigarette companies have found no reason to believe that the use of ingredients in cigarettes could be harmful to the smoker.

In addition, HHS will evaluate the list of ingredients submitted by industry and is charged by Congress with preparing a report on ingredients. We see no reason to create an additional review mechanism.

B. Possible QA's for PME.

1.

Q : Are you aware that the US authorities have asked the US companies to submit a list of ingredients used in cigarettes to HHS ? And if so, what is your comment ?

A : The six leading cigarette manufacturers of the US have provided an extensive list of ingredients which was consolidated by Covington and Burling, a Washington D.C. law firm and submitted to HHS on 2nd April, 1986. Other manufacturers and importers submitted information on ingredients independently to the HHS.

There are national regulations on the use of ingredients in cigarettes in some European countries which contain minor differences of detail, mainly due to historic developments

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and local taste preferences. It is for this reason quite likely that some ingredients which are contained in the US list are not found in some of the European lists.

However, the vast majority of ingredients used in cigarettes are internationally the same.

Philip Morris has always strictly complied with all national regulations when manufacturing or importing cigarettes into a particular country, and Philip Morris is continuing to do so in the future.

2.

Q : Does the list submitted by the US cigarette industry to HSS contain any ingredients which are not authorised in Germany, Great Britain, France, or any other European country ?

A : National European regulations on the use of ingredients in cigarettes show also minor differences, mainly due to historic developments and local taste preferences. It is for this reason quite likely that some ingredients found in the US list are not contained in some of the European lists.

However, the vast majority of ingredients used in cigarettes are internationally the same.

Philip Morris has always strictly complied with all national regulations when manufacturing or importing cigarettes into a particular country, and Philip Morris is continuing to do so in the future.

3.

Q : Are you embarrassed by the fact that the US list of ingredients was published at this point in time ?

*This should
be reviewed
as to accuracy.
It also may
work against
our position
that ingredients
list should
be trade secret.*

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[A : Not at all. Many European countries have had for quite some time regulations or authorised lists of ingredients for the use in cigarettes. Although there are minor country to country variations, the vast majority of ingredients are contained in all lists.

Philip Morris has always strictly complied with all national regulations when manufacturing or importing cigarettes into a particular country, and Philip Morris is continuing to do so in the future.

4.

Q : Is it not true that the majority of cigarettes in some European markets are manufactured without the use of any ingredients ?

A : European markets differ considerably from each other in terms of consumer preferences. This was particularly so in the past, when virtually each country had cigarettes with a particular taste orientation. These different tastes had evolved in conjunction with specific local types of food and beverages. In traditional cigarettes, the specificity of taste was achieved largely by blending selected types of tobacco. Some of these tobaccos have a very intensive taste which is incompatible with additional flavouring. However, during the recent decades modern blended type cigarettes, which contain ingredients for flavouring purposes and which have more subtle taste characteristics, have become more popular in virtually all markets.

5.

Q : Do the authorities in European countries regulate the use of materials other than ingredients which are used in the manufacture of cigarettes, e.g. adhesives, and how do

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companies comply with these regulations, given the fact that there are national differences ?

A : Fortunately, the regulations which exist in different countries are fairly compatible. As a rule, Philip Morris takes those regulations which are legally binding in certain countries as guidelines for product specifications in those countries where no specific legislation exists. In many European countries there are formal or informal established consultation procedures in which the concerned segments of the public provide information on specific issues to the authorities. Whenever appropriate and within established procedures, the cigarette manufacturers have provided technical information to authorities in the past, and there is no reason to doubt that they will do so in the future.

In fact, Philip Morris has always strictly complied with all national regulations when manufacturing or importing cigarettes into a particular country, and Philip Morris is continuing to do so in the future.

6.

Q : Why are pesticides not included in regulations concerning ingredients used in cigarettes ?

A : [This question really ought to be addressed to the authorities concerned. However,] The Federal Republic of Germany has the most stringent legal regulations (Food Law in conjunction with the Pesticides Ordinance) concerning maximum permitted pesticide residue levels in tobacco products. The cigarette companies have actively cooperated with the German authorities in developing specific testing methods for pesticide residues present in tobacco. They covered those substances which were used anywhere in the

Suggest deletion of bracketed material.

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world by tobacco growers (frequently so upon advice of their agricultural authorities). Thousands of tobacco samples were analysed stretching over many crop-years, providing a representative geographic coverage and including all major commercial tobacco types. In this way, reliable statistics on the actual pesticide residue levels in cured commercial tobaccos were established. The German authorities have based their regulations to a large extent on the information provided by the cigarette companies.

Philip Morris uses the German regulations on maximum permitted pesticide levels as internal guidelines throughout the company. In addition, Philip Morris' leaf experts assist tobacco growers world-wide, whenever appropriate, in providing information on the correct use of pesticides in the cultivation of commercial tobaccos.

7.

Q : Can the compliance with regulations on the use of ingredients and other materials in cigarettes be enforced by the authorities ?

A : Generally speaking, two factors are operational in this area. Authorities do perform controls in the form of sampling from the market place, from storage facilities or during inspections of factories. In addition, companies check each others compliance with regulations for competitive reasons.

[It must be appreciated that the success of any measures to enforce legal regulations depends to a considerable extent on the availability of suitable testing procedures.]

Over decades, cigarette companies have developed analytical

Presumably
cigarette.

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methodologies covering all aspects of tobacco and smoke chemistry. The resulting data were, as a rule, presented in scientific meetings such as CORESTA and TCRC, or published in internationally recognised journals such as "Beiträge", the CORESTA Proceedings, etc. Today, a vast arsenal of sophisticated scientific methods is available to testing institutions. The cigarette companies have thus acted with responsibility and demonstrated due diligence.

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